

Applicant : Daniel M. LaFontaine
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Filed : October 27, 2003
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Attorney's Docket No.: 10527-430002 / 00-0145-CON

REMARKS

The Applicant thanks the Examiner for the attention to this matter. Claims 1-20 are pending and stand rejected. The Applicant has amended each independent claim, and several of the dependent claims, and believes that the claims as amended are in condition for immediate allowance.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claim 13 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claim 13 to more clearly claim the invention, and submits that it is in condition for allowance.

Rejections under 35 U.S.C. § 103 over Lafontaine and Ressemann

The Examiner rejected claims 1, 2, 5, 6, 8-11, and 13-19 under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine ('735) in view of the teaching of Ressemann et al. ('958). Claims 1 and 16 are the independent claims in this group, and both have been amended here. Claim 1 recites a cryoplasty apparatus having a catheter with a cooling member disposed at one end, a pull cord arranged to pull the cooling member proximally, and a sheath that couples the pull cord and the catheter. Claim 16 recites a cryoplasty apparatus comprising a catheter, a cooling member disposed at the distal end of the catheter, a pull cord to pull the cooling member proximally, and a sheath that couples the pull cord and the catheter and includes a first lumen for the pull cord and a second lumen for the catheter.

Lafontaine '735 discloses a cryoplasty device and method. In one example, the device is a catheter 10 with a shaft 12 having a dilatation balloon 14 at its distal end, and a temperature sensor 22 on the balloon. Ressemann '958 discusses a catheter having a tip body 76 that follows a guide wire 78 as the catheter is advanced. The Ressemann '958 patent notes that the catheter is advanced along, and slides over, the guide wire. (*See, e.g.*, Ressemann '958, col. 5,

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line 51 to col. 6, line 15). Thus, Ressemann does not recite a pull cord that pulls a cooling member proximally, as recited in all the pending claims. The guide wire in Ressemann slides, and does not pull at all. (*See, e.g.*, col. 5, line 51 to col. 6, line 15). Thus, the Ressemann catheter is not steerable, and is not directed in any way at the subject matter of the pending claims.

Moreover, the office action merely cites the combination of Lafontaine and Ressemann as a foregone conclusion, but points to no motivation to combine the two references. At bottom, the guide wire 78 is merely a guide wire; it is not a pull cord for pulling a cooling member proximally, and nothing in Ressemann teaches or suggests modifying Lafontaine to produce the claimed invention.

For each of these reasons, the Applicant respectfully requests withdrawal of the rejection of claims 1, 2, 5, 6, 8-11, and 13-19.

Rejections under 35 U.S.C. § 103 over Lafontaine, Ressemann, Milder, and Stern

The Examiner rejected claims 3, 4, and 20 under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine ('735) and Ressemann et al. ('958) as applied to the claims above, and further in view of the teachings of Milder ('215) and Stern et al. ('470). Each of these claims is a dependent claim that adds, to its respective independent claim, the requirement that the cooling member comprise "at least one electrode" or "at least one pad printed conductive electrode."

The Examiner relies on Lafontaine and Ressemann for the disclosure discussed in the rejection above, and relies additionally on Milder as teaching "that it is generally known to associate sensing/treatment electrodes in a cryosurgical device." (Office Action, at 4). The Examiner recognizes, however, that the Milder device does not include a balloon. (*Id.*). The Examiner relies on Stern as teaching "providing sensing/treatment electrodes on a balloon structure which is filled with a fluid." (*Id.*) The Examiner concludes from these disparate teachings that it would have been obvious to provide the Lafontaine balloon with a conductive

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pad electrode (per Stern) to allow for the sensing and treatment of tissue during the cryogenic procedure.

As an initial matter, these rejections depend on a conclusion that Ressemann somehow discloses or suggests a pull cord coupled to the cooling member and adapted to pull the cooling member proximally. As noted above, it does not. For this reason alone, Applicant requests withdrawal of these rejections.

Applicant also respectfully suggests that the rejections are improper for another, independent reason. In particular, Milder merely shows one particular way to use an electrode on a cryosurgical device; it does not show or suggest that an electrode should be used to modify the devices of Lafontaine or Ressemann, and certainly does not show such a modification so as to obtain the invention of the pending claims. Moreover, Stern's invention is directed to an entirely different application, and contains no suggestion whatsoever that the device that it discusses could or should somehow be combined with the devices of Lafontaine, Ressemann, and Milder. Any rejection based on these references is an impermissible use of the pending claims to build a hindsight reconstruction of the present invention, because there is no motivation in any of the references to make the combination that is made in the rejection. *See In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998) ("[T]he suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness."). Because no motivation to combine has been identified, no prima facie case of obviousness has been made. *See, e.g., In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). For this reason also, Applicant respectfully requests that the rejection of claims 3, 4, 21, 22, 39 and 40 be withdrawn.

Rejection for Obviousness-Type Double Patenting

The pending claims stand rejected under the doctrine of obviousness-type double patenting. The Applicant will execute an appropriate terminal disclaimer when allowable subject matter is indicated.

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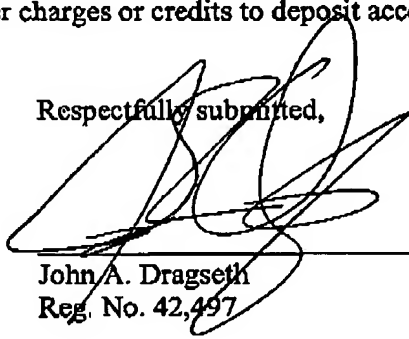
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The Applicant submits that the pending claims, as amended, set forth subject matter that is neither disclosed in, nor fairly suggested by, the cited art. As a result, the Applicant respectfully requests allowance of the pending claims.

Please charge Deposit Account No. 06-1050 in the amount of \$1,020 for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 12-5-05


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